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Spring 1997

ADVERSE REACTIONS TO NATURAL RUBBER LATEX

By Vesna J. Tomazic, Ph.D.

In response to the highly infectious hepatitis B virus (HBV) and the appearance of the human immuno-deficiency virus (HIV), the Occupational Safety and Health Administration (OSHA) issued a Universal Pre-cautions Standard in the 1980s, requiring all health care workers to use protective equipment. Since then, medical gloves have been the primary source of barrier protection for healthcare workers and others such as those in the waste disposal industry, janitors, and police. When HIV became a serious health threat, there was a ten-fold increase in the number of gloves used in the United States. Most medical gloves are made of natural rubber latex (NRL).

With such a dramatic increase in the demand for medical gloves and the longer and more frequent use of gloves, the number and the severity of adverse reactions to NRL have increased greatly. In the past, occasional

problems with NRL were reported to the Food and Drug Administration (FDA) and appeared in the scientific literature, but there was little public concern. After a decade of intensive use of NRL gloves, many of which are now supplied from new, less-controlled sources, adverse reactions to NRL are reaching almost epidemic proportions. To prevent or solve the problem, manufacturers and users will need extensive education in the new diagnostic testing and manufacturing technologies for NRL products.

What kinds of reactions are caused by NRL products?

Three types of adverse reactions may develop as a result of frequent and prolonged exposure to NRL: irritant contact dermatitis, allergic contact dermatitis, and urticaria/anaphylaxis.

(Continued on page 2)

NATURAL RUBBER LATEX ALLERGY: A MEDWATCH SUCCESS STORY

By Sharon F. Dillard, M.S., A.A.R.T. (N), C.N.M.T.

It is not always easy to identify medical device issues that have significant public health implications. That is why the Food and Drug Administration (FDA) maintains the voluntary MedWatch reporting system and relies on healthcare professionals to help identify emerging medical device problems. The easiest medical device problems to identify are simple mechanical failures that occur many times in one location. The hardest problems to recognize are patient problems that are unusual, occur infrequently at many different user sites, and cannot be easily linked to a specific product. The latter was the case with allergic and anaphylactic reactions to medical devices with components made from natural latex/natural rubber (NLNR).

FDA investigations, which ultimately identified NLNR allergy as an emerging public health concern, were started in response to VOLUNTARY reports sub-mitted by physicians, nurses, and technologists. The first reports described

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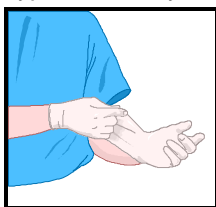
In This Issue:

Adverse Reactions to Natural Rubber Latex.....	1
Natural Rubber Latex Allergy.....	1
How FDA Regulates Gloves.....	4
FDA Scientists Study QA Tests for Latex Gloves.....	5
FDA Clarifies Latex Terminology.....	6
Glove Quality And Selection Criteria.....	7
FDA Alerts Users of Reusable Medical Devices.....	7

Adverse Reactions To Natural Rubber Latex - (from page 1)

Irritant Contact Dermatitis (ICD) is a direct injury to the skin caused by chemicals, added to NRL during manufacturing, that remain on the surface of finished products. These chemicals injure the skin and cause redness and swelling, some-times accompanied by itching and a burning sensation. The first symp-toms appear shortly after exposure, in the range of several minutes to 6 hours. If the source of irritation is eliminated, symptoms will clear in several hours. With chronic ex-posure, however, symptoms will worsen and the skin will become dry, thickened and cracked. The intensity of the reaction depends on the dose and duration of exposure and the skin condition at the time of exposure. There is no known genetic factor that links susceptibility to this type of irritation.

Allergic Contact Dermatitis (ACD) is an immunological response to chemicals on NRL products that penetrate the user's skin and bind to the user's own proteins. This is called delayed or Type IV hypersensitivity or chemical sensitivity. The dose of chemicals, frequency of exposure, and skin condition are among the most important factors in causing sensitization. The symptoms of Type IV hyper-sensitivity include redness and



swelling, which can appear 1 to 3 days after exposure and can last for several days. With each exposure, the individual becomes more sen-sitized, and the reaction becomes more intense. In severe cases, the sensitivity reaction will include thickened skin, pimples, blisters, and other skin sores.

Two major characteristics distinguish ICD from ACD. ICD develops shortly after exposure, while ACD usually develops 1 to 3 days later and lasts longer than ICD. Second, ICD is always confined to the area of exposure; ACD may ex-tend beyond the area of exposure, even on distant skin areas.

Urticaria and Anaphylaxis are clinically dissimilar reactions, but both are manifestations of the same type of hypersensitivity referred to as Type I or Immediate. Type I hypersensitivity is also an immuno-logical

reaction; in contrast to contact dermatitis, it is caused by proteins present in raw NRL. Some of these NRL proteins remain on finished NRL products, regardless of the manufacturing processes. With use of the NRL products, the proteins may penetrate the user's skin or any other body tissue that may be directly exposed. The proteins may cause antibody production that increases with each subsequent exposure. A number of exposures may occur be-fore any clinical symptoms appear.

The type and severity of reaction depend on the level of sensitivity, the amount of allergen, and the site of exposure. If contact with the aller-gen is through the skin, urticaria can develop in 10 to 30 minutes after exposure. The appearance of the skin reaction differs clearly from the appearance of ACD or ICD. Urticaria is characterized by pink hives and swelling, often accom-panied by itching and tingling. A respiratory exposure to the allergen could result in a runny nose, wheez-ing, and difficulty in breathing.

Anaphylaxis, the most severe Type I allergy reaction that may appear in individuals sensitive to NRL proteins, occurs if the allergen is introduced directly into the blood. Anaphylaxis is a potentially life -threatening reaction characterized by facial swelling, difficulty in breathing, rapid heart rate, and a severe drop in blood pressure. Rapid interven-tion with antihistamine drugs will relieve the symptoms relatively quick-ly. If the appropriate therapy is not given, anaphylaxis may be fatal.

Type I allergy is also linked to genetic factors, making some individuals more sensitive than others. Therefore, individuals who have other allergies and are fre-quently exposed to NRL proteins would be at the highest risk to develop an allergy to NRL, usually after multiple exposures. Only about 1% of the general population is affected by this problem. However, the highest prevalence of Type I latex allergy (5% to 15%) is found in occupationally exposed individuals, such as healthcare providers and hospital personnel. It is also known that allergens in NRL have some similarity to those in chestnuts and some tropical fruits such as kiwi,

avocado, and bananas. Therefore, individuals with fruit allergies may react to NRL products without ever having a previous reaction to NRL. Likewise, allergic reaction in NRL-sensitive individuals may be triggered by fruit consumption.

Which diagnostic tests are available and appropriate?

Identification and proper diag-nosis of adverse reactions to NRL is an essential step for determining proper medical treatment and proper behavioral patterns to pre-vent further reactions. A review of the medical history and an accurate

(Continued on page 3)

Adverse Reactions To Natural Rubber Latex - (from page 2)

description of the symptoms may pinpoint the specific type of allergy and indicate appropriate testing. In some cases, frequently exposed individuals with a diagnosed Type IV allergy may also subsequently develop a Type I allergy.

Patch Test. When irritant or allergic contact dermatitis is suspected, the patch test is a common diagnostic tool. Shielded application of the test material to intact skin will identify sensitized individuals. Irritant contact dermatitis can be distinguished from allergic contact dermatitis by the time of onset and duration of the skin reaction.

Skin Prick Test. This is the preferred test method in the diagnosis of Type I allergy to latex proteins. NRL proteins are introduced through the skin by skin puncture. If an individual is sensitized, a reaction will develop in 15 to 20 minutes and is graded according to the diameter of redness and the swelling at the test site.

RAST Test. This is an in vitro test for detection of allergen-specific antibodies in a patient's blood (Type I). Recent technical improvements have increased the sensitivity of the test, making it a simple and reliable test for detection of sensitized individuals. The advantage of this in vitro test is that it can identify sensitization before the appearance of clinical symptoms. However, if the RAST test is positive, it should be followed by the skin test to confirm and to grade the level of sensitivity. Healthcare workers and other individuals frequently exposed to NRL products are encouraged to be tested regularly.

How can reactions be prevented?

In the case of irritant contact dermatitis, it may be helpful to identify different types of gloves and switch from one to another. A similar approach may be used for allergic contact dermatitis. Manufacturers, aware of this problem, have manufactured products with reduced amounts of residual chemicals and labeled them "Hypoallergenic." In general, such gloves are an improvement and can be used by individuals who have had reactions to other gloves. However, to avoid possible confusion with protein allergy, the label "Hypoallergenic" will soon be replaced with a statement that clearly indicates a reduced content of sensitizing chemicals.

Type I allergy to NRL proteins is complicated. Severely sensitized individuals may develop a reaction to minute amounts of allergen. Manufacturers are making efforts to reduce the protein levels on their NRL products; but, it is not presently possible to make a "protein-free" latex product, or to measure extremely small amounts of protein on the products. With presently available methodology, reliable measurement cannot be made below 50 µg protein/g of NRL, an amount that may still cause a reaction. Therefore, for highly sensitized individuals, avoidance of NRL products is presently the only safe measure. Considering the wide use of rubber in medical and consumer products, this may be an extremely difficult task. FDA is issuing a rule requiring

manufacturers of NRL medical devices to label all their products accordingly.

For other frequent users of NRL devices, a careful selection of low protein products is very important to prevent further sensitization. FDA has recently cleared for marketing a number of gloves that claim a minimum measurable level of protein (less than 50 µg/g of NRL). These gloves would be less likely to sensitize individuals but may still cause a reaction in those already sensitized. Both the American College of Allergy and Immunology and the American Academy of Allergy and Immunology have issued recommendations for diagnosis of NRL allergy and prevention procedures for hospitals and healthcare settings. Many hospitals have already developed specific procedures for NRL-sensitive patients and hospital personnel. ♦

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PLEASE DO NOT SEND FAILED DEVICES TO FDA

Although it is important for FDA to learn of adverse incidents caused by medical devices, only a written report is necessary. We do NOT need to receive and inspect the device.

Natural Rubber Latex Allergy - (from page 1)

patient deaths that occurred during barium enema procedures, before the administration of barium. These initial voluntary reports from vigilant and concerned healthcare professionals provided critical information that resulted in the identification of NLNR allergy as the probable cause of the reported events. Additional reports received from healthcare professionals – in response to a special FDA request for any information related to NLNR problems – provided enough information for FDA to issue a Medical Alert to raise clinical awareness of NLNR allergy issues. FDA has proposed a NLNR labeling regulation, participates in voluntary standards activities for medical gloves, has begun collaborative research on NLNR allergy-related issues, and has co-sponsored an international conference on latex sensitivity.

FDA continues to receive many calls from healthcare professionals requesting information on NLNR allergic and anaphylactic incidents. Since FDA began efforts to inform healthcare professionals about

reactions to NLNR, we have received numerous reports from a number of sources about reactions to various other NLNR-containing medical devices.

FDA has received over 1,000 allergic and anaphylactic reaction reports on NLNR patient examination and surgeon's gloves. These reports are unique because most are from healthcare professionals reporting their own reactions. In response, FDA conducted research and published two articles entitled "Prevalence of Latex-Specific IgE Antibodies in Hospital Personnel"⁽¹⁾ and "Short Analytical Review: Latex-Associated Allergies and Anaphylactic Reactions."⁽²⁾ FDA continues to work with device manufacturers and other Federal agencies responsible for occupational health concerns regarding latex sensitivity. On June 23, 1997, the National Institute for Occupational Safety and Health (NIOSH) released an alert entitled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace." You can obtain copies of this document by calling 1-800-356-4674 or by visiting the

NIOSH home page on the World Wide Web at:

<http://www.cdc.gov/niosh/homepage.html>

Remember that your observations regarding device problems are critical to FDA's mission to protect the public health. Your voluntary and mandatory MedWatch reports do make a difference. Keep up the good work. ♦

⁽¹⁾Kaczmarek, R.G., Silverman, B.G., Gross, T.P., et al., *Annals of Allergy, Asthma, and Immunology*, 1996, 76: 51-56.

⁽²⁾Tomazic, V.J., Withrow, T.J., Fisher, B.R. and Dillard, S.F., *Clinical Immunology and Immunopathology*, 1992, 64 (2): 89-97.

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HOW FDA REGULATES GLOVES

by Terrell A. Cunningham, R.N.

Good Manufacturing Practices. Manufacturers of medical gloves are required to meet Good Manufacturing Practices (GMPs) for medical devices. The GMP regulation requires that every manufacturer prepare and implement a quality assurance (QA) program that is appropriate for the type of glove being manufactured. QA programs specify such items as proper cleaning and maintenance of equipment; monitoring and control of the manufacturing process; and identification of specific glove defects, their causes, and any actions necessary to correct the problem. Also, part of the GMP compliance requires manufacturers to test their gloves to

make sure they meet the acceptable quality level (AQL) and quality claims when delivered to customers.

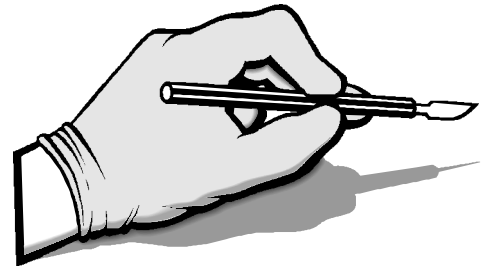
Required Labeling. All medical gloves must be labeled with specific information. Examples of the type of labeling required on glove packaging include country of origin and adequate directions for use. In June 1996, a proposed rule for latex content labeling was issued. When this proposed rule becomes final, all

(Continued on page 6)

FDA SCIENTISTS STUDY QUALITY ASSURANCE TESTS FOR LATEX GLOVES

By Ron Carey, Ph.D., and Dave Lytle, Ph.D.

Two types of latex gloves are used in healthcare facilities: patient examination gloves and surgeon's gloves. The Food and Drug Administration (FDA) tests sample lots of gloves from domestic manufacturers and gloves being imported into the U.S. FDA and the manufacturers use the current American Society for Testing and Materials (ASTM) standard test for quality assurance of gloves. To detect holes in gloves, the gloves are filled with water and then examined for two minutes. Any water appearing on the outside of the glove is considered a leak and the glove fails.



For FDA, the acceptable quality level (AQL) is not more than 2.5% failure of the surgeon's gloves and not more than 4% failure of the patient examination gloves. Lots that fail a manufacturer's or FDA's test must be reconditioned and brought into compliance or destroyed. The sensitivity of this water test can be judged by testing surgeon's gloves that have holes deliberately made with a laser. Using this method, we can detect 40 micron (a micron = 0.0016 inch) holes in the fingers and approximately 20 micron holes in the palms. Gloves are intended to prevent the transfer of fluid between medical personnel and patients. Viruses found in blood, sweat, and other fluids are much smaller than the holes detectable by the water leak test. For example, the human immunodeficiency virus (HIV) is about 0.1 micron in diameter. The function of the water leak test is not to detect holes as small as HIV, but to provide quality assurance (QA), i.e., to assure manufacturers that their gloves are made as flawless as possible.

To further test the gloves' ability to be penetrated by viruses, we filled gloves with a virus/saline suspension. Then, each finger was dipped into saline to see if any virus leaked out. Some small holes (as small as 2 microns) were detected in addition to those found with the water test. We concluded that most of the risk of exposure comes from the larger pinholes and that the risk from the smaller holes was not significant enough to warrant changing the ASTM test to one that could detect these smaller holes.

Other scientists performed additional tests on gloves that had been used in a clinic or in surgery. These tests have shown that most of the unwanted exposure to fluids comes from tears and breaks occurring during use. Leakage through pinholes that are not detected by QA tests is relatively unimportant. However, it is possible that holes present before use may act as initiation sites for the tears and breaks.

An individual's risk of infection is related to the frequency and amount of exposure to virus-containing fluids. Given the small but finite possibility of infection via pinholes and the larger problem of tears and breaks, it is reasonable to consider changes in the AQL at this time to reduce unwanted exposure. Glove users should keep in mind that double gloving and intact skin beneath the gloves will continue to reduce the risk.

FDA will continue to monitor QA procedures for gloves with the goal of minimizing the potential for exposure to infectious agents for both healthcare workers and their patients. We will continue to research the reasons for glove failures and to determine if these failures are critical in infection control. FDA is working with ASTM to raise QA standards when needed. ♦

Dr. Carey is Chief of the Hydrodynamics and Acoustics Branch in the Division of Physical Sciences. Dr. Lytle is a biophysicist in the Division of Life Sciences. Both are in CDRH's Office of Science and Technology.

How FDA Regulates Gloves - (from page 4)

manufacturers of latex-containing products will be required to provide latex content information on their product label.

Special Labeling Claims. In addition to required labeling, manufacturers may label gloves with claims of special attributes such as color, thickness, absence of powder, and latex content. Claims for these attributes must meet certain specifications or guidelines as outlined in FDA guidance or recognized industry standards. Manufacturers must submit data to FDA to support these labeling claims, and all claims must be cleared before marketing.

Surveillance Sampling. FDA inspects samples of gloves at the port of entry into the United States using the water leak test method. Even though some imported gloves may have passed the water leak test at the manufacturing site, the gloves may not pass the same test once they reach the U.S. If they fail the U.S. testing, the gloves cannot be sold. Sample lots of gloves manufactured in the U.S. are also periodically tested by FDA using the water leak test method.

Stability and Expiration Dating. Gloves from some manufacturers have longer stability than others. To help reduce this problem, FDA asked the American Society for Testing and Materials (ASTM) to modify its standards to require initial testing and periodic follow-up testing to verify that gloves will pass the water leak test after accelerated or real-time aging. In 1995, ASTM began to study the degradation of gloves in order to assess and improve existing standards.

FDA is conducting a feasibility study to determine whether or not using an accelerated aging test can predict

the shelf life of medical gloves. Currently, if a manufacturer wants to put an expiration date on the label, FDA requires real-time aging of medical gloves to support the expiration date. FDA is also evaluating the environmental degradation of natural rubber latex (NRL) gloves.

Guidance to Manufacturers. FDA has produced guidance documents such as "Guidance for Medical Gloves: A Workshop Manual" to help manufacturers meet FDA requirements and to improve the quality of medical gloves in the marketplace. FDA also conducts training courses that encourage manufacturers to improve the overall quality of medical gloves by complying with voluntary ASTM standards and equivalent international standards.

Medical Device Reporting. FDA has both mandatory and voluntary systems for reporting of adverse incidents with medical devices. Manufacturers and device distributors are required to report to FDA when they become aware of any device-related death, serious injury, or malfunction that could cause serious injury if the malfunction were to recur. User facilities are required to report device-related deaths to FDA and the manufacturer and serious injuries to the manufacturer. Healthcare professionals and consumers may report any device-related concern to FDA through the MedWatch Program by calling 1-800-FDA-1088. FDA monitors adverse event reports related to medical gloves and reviews and acts upon them as appropriate. ♦

Terrell Cunningham is a nurse consultant in CDRH's Office of Device Evaluation.

FDA CLARIFIES LATEX TERMINOLOGY

There is inconsistency in the terminology used to describe the raw agricultural materials and the products made from various intermediate forms (e.g., natural rubber latex and dry natural rubber); synthetic latex and synthetic rubber to which natural rubber has been added; and synthetic latex and synthetic rubber that contain NO natural rubber. The following terms are used in the *Bulletin*:

"Natural latex" (NL) is defined as a milky fluid that consists of extremely small particles of rubber obtained from a rubber tree. It contains a variety of substances and plant proteins thought to be primary allergens.

"Natural rubber" (NR) includes all materials made from or containing natural latex. Natural rubber containing products are made using two

common Processes: the Natural Rubber Latex (NRL) process and the Dry Natural Rubber (DNR) process.

The phrase "contains natural rubber" includes NRL and DNR products as well as any synthetic latex or synthetic rubber that contain natural rubber. This definition does not include any synthetic latex or synthetic rubber product that contains NO natural rubber. ♦

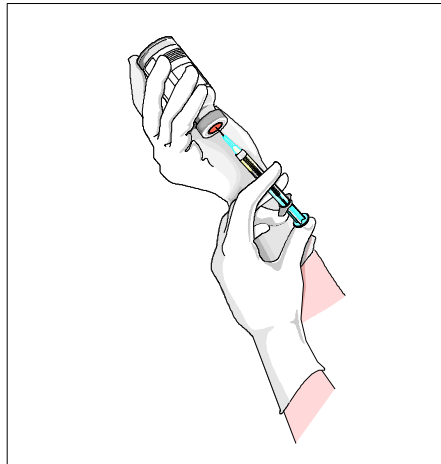
GLOVE QUALITY AND SELECTION CRITERIA

By Vesna J. Tomazic, Ph.D.

When selecting protective gloves for use in a healthcare setting, users should consider the balance between expected risk and benefit. While adequate protection from infectious agents is the primary concern, the adverse effects caused by the individual's repeated use of natural rubber latex (NRL) gloves are also important. If the barrier properties are damaged, infectious agents and hazardous chemicals can pass through to the skin and cause infection, skin irritation or injury, or severe allergic reactions. Use of alternative products may reduce risk of adverse reactions, but these may also increase the risk of barrier failure.

The intended use of a glove determines the type of glove needed. Variables include the potential for exposure to hazardous materials and infectious agents, the frequency of glove use, and the duration of a single use. Some of the selection criteria are:

- general material qualities, such as elasticity, sterility, shelf life, and defects in material;
- barrier properties such as lack of holes in gloves, durability (for extended use), resistance to physical stress (tension, friction, contact with hard and sharp objects), resistance to temperature changes and to chemicals; and
- low level of sensitizing chemicals and allergenic proteins on the gloves (of critical importance in a heavy glove use environment and with high-risk groups).



Although problems may be encountered with the NRL in gloves, it is considered reliable for its barrier properties, elasticity, and excellent tactile sensation. Other glove materials and formulations may be used by individuals who cannot use NRL. In the past, vinyl gloves were found to be inferior to NRL in barrier properties. Presently, several types of non-NRL gloves, including synthetic rubber, are available. These are significantly improved in quality and can be a good substitute for NRL-sensitized individuals.

Allergic reaction is still the most serious problem with NRL gloves, even though manufacturers have improved the product significantly by substantially reducing the protein levels. The safe threshold level is not known, but we do know that less protein means a reduction in sensitivity of users. ♦

Vesna J. Tomazic is a Biologist/Immunologist in CDRH's Division of Life Sciences, Office of Science and Technology.

FDA ALERTS USERS OF REUSABLE MEDICAL DEVICES

By Lily Ng, R.N, M.S.N, M.P.H, and Mary Ann Wollerton, M.P.A.

Medical devices that are rented or leased from third parties or exchanged with other healthcare facilities may not be properly cleaned, disinfected, or sterilized before they are delivered. FDA does not know how often this occurs or which devices are most likely to be involved. However, the problem is serious enough to alert healthcare personnel about this improper handling of devices between uses. Devices that are not processed correctly can contaminate the facilities, the healthcare providers, and the medical device couriers with infectious biohazardous material. Also, any organic material that remains on the devices may compromise the effectiveness of sterilization procedures.

Sometimes rental/leasing contracts between healthcare facilities and third parties fail to clearly identify who is to clean, disinfect, and/or sterilize the used devices. Often, there is no written contract.

FDA recommends to healthcare facilities the following:

- Review all rental/lease contracts to ensure that the parties responsible for cleaning, disinfecting, and/or sterilizing are identified;
 - If the healthcare facility is responsible, it should adequately train and properly equip its personnel to properly clean, disinfect, and sterilize;
- (Continued on page 8)

FDA Alerts Users of Reusable Medical Devices -(from page 7)

- If a third party is responsible, the healthcare facility should make sure that the company has adequate equipment, procedures, and personnel to clean, disinfect, and sterilize properly. It is also important that the company follow the device manufacturer's instructions during these three procedures;
- If the third party is responsible, the healthcare facility should teach its personnel how to correctly handle, package, and label contaminated devices for shipment back to the supplier; and
- If the third party also reprocesses or refurbishes medical devices, the healthcare facility should ensure that the company knows the device manufacturer's specifications for each product. Healthcare facilities may wish to establish quality assurance procedures to ensure that reprocessed and refurbished devices fulfill these specifications.

FDA is collecting data on this reuse problem. Please report any related adverse events to FDA's MedWatch voluntary reporting program by mail: MedWatch, HF-2, 5600 Fishers Lane, Rockville, Maryland 20857; by FAX: 1-800-FDA-0178; or by telephone: 1-800-FDA-1088.

If you have any questions regarding this article, please contact Nancy Pressly, by mail at CDRH/OSB, HFZ-510, 1350 Piccard Drive, Rockville, MD 20850; by FAX at 301-594-2968; or by e-mail at nap@cdrh.fda.gov. ♦

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